

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P.,  
NAPP PHARMACEUTICAL GROUP LTD.,  
BIOVAIL LABORATORIES INTERNATIONAL,  
SRL, and ORTHO-MCNEIL, INC.,

Plaintiffs/Counterclaim-defendants,

v.

PAR PHARMACEUTICAL, INC. and  
PAR PHARMACEUTICAL COMPANIES, INC.,

Defendants/Counterclaim-plaintiffs.

C.A. No. 07-255-JJF  
(CONSOLIDATED)

**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO STRIKE  
DEFENDANTS' EXPERT REPORT OF HARRY F. MANBECK, JR.**

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**TABLE OF CONTENTS**

	<b>Page(s)</b>
I. NATURE AND STAGE OF THE PROCEEDINGS.....	1
II. SUMMARY OF ARGUMENT .....	1
III. STATEMENT OF FACTS.....	2
A. The Litigation .....	2
B. Mr. Manbeck’s Expert Report .....	3
IV. ARGUMENT .....	5
A. Patent Law Experts Are Routinely Precluded From Testifying Because Their Proposed Testimony Invades The Province Of The Court .....	5
B. Mr. Manbeck Cannot Testify About Materiality Because He Is Not Qualified To Testify About The Underlying Technology .....	8
C. Mr. Manbeck’s Opinions About Alleged Intent To Deceive The PTO Are Not Proper Expert Testimony .....	9
V. CONCLUSION .....	9

# **TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>CASES</b>	
<i>Abbott Labs. v. Syntron Bioresearch, Inc.</i> , No. 98-CV-2359 H(POR), 2001 WL 34082555 (S.D. Cal. Aug. 24, 2001).....	8
<i>Berry v. City of Detroit</i> , 25 F.3d 1342 (6th Cir. 1994) .....	6
<i>Corning Inc. v. SRU Biosystems</i> , C.A. No. 03-633-JJF, (D. Del. Nov. 5, 2004).....	7
<i>Digital Control, Inc. v. Charles Mach. Works</i> , 437 F.3d 1309 (Fed. Cir. 2006).....	1, 8
<i>F. Hoffman-La Roche, Ltd. v. IGEN International, Inc.</i> , C.A. No. 98-318-JJF, Tr. at 64 (D. Del. Oct. 24, 2000) .....	7
<i>L’Oreal S.A. v. Revlon Consumer Prods. Corp.</i> , C.A. No. 98-424-SLR, (D. Del. Feb. 24, 2000).....	6
<i>Lucas Aerospace, Ltd. v. Unison Indus., L.P.</i> , C.A. No. 93-525-JJF, (D. Del. Mar. 9, 1995) .....	6
<i>Ondeo Nalco Co. v. EKA Chems., Inc.</i> , C.A. No. 01-537-SLR, (D. Del. Mar. 21, 2003) .....	6
<i>Revlon Consumer Prods. Corp. v. L’Oreal S.A.</i> , No. 96-192 MMS, 1997 U.S. Dist. LEXIS 4117 (D. Del. Mar. 26, 1997).....	7
<i>Thorn EMI N. Am., Inc. v. Micron Tech., Inc.</i> , C.A. No. 92-673-RRM, Tr. at 32-34 (D. Del. Nov. 23, 1993) .....	7
<i>United States v. Scop</i> , 846 F.2d 135 (2d Cir. 1988).....	6, 9
<b>STATUTES</b>	
35 U.S.C. § 102(e) .....	5
<b>OTHER AUTHORITIES</b>	
37 C.F.R. § 1.56(a).....	8
Fed. R. Evid. 702 .....	5, 9

## **I. NATURE AND STAGE OF THE PROCEEDINGS**

Plaintiffs filed this patent infringement action under the Hatch-Waxman Act on May 9, 2007, after receiving a notice letter from Defendant Par Pharmaceutical, Inc. that it sought approval to market a generic copy of Plaintiffs' Ultram<sup>®</sup> ER, a controlled release formulation of tramadol, an analgesic. A bench trial is scheduled to begin on November 10, 2008. (D.I. 23.) Pursuant to the Stipulated Scheduling Order, as modified (D.I. 130, D.I. 156 and D.I. 166), the parties exchanged opening expert reports on July 25, 2008. Among the expert reports served by Defendants ("Par") was a 70 page report from a purported "patent law expert," Harry F. Manbeck, Jr. (the "Manbeck report"). Plaintiffs move to strike the Manbeck report and preclude Mr. Manbeck's testimony.

## **II. SUMMARY OF ARGUMENT**

The Court should strike Mr. Manbeck's report and testimony in its entirety. Par seeks to call Mr. Manbeck at trial to offer testimony concerning an "overview" of the patent prosecution process, a recitation of the pertinent law, his legal opinion on what constitutes prior art, his views on what the alleged prior art discloses, his opinions on materiality, and his view that the patentees allegedly withheld, misrepresented or omitted material information from the Examiner.

The issue of inequitable conduct requires proof that material misrepresentations were made to or material information was withheld from the Patent and Trademark Office ("PTO") and proof of intent to deceive the PTO. *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006). The Manbeck report contains (1) improper opinions on the law regarding what qualifies as prior art -- an ultimate issue for the Court, (2) improper opinions regarding materiality based on Mr. Manbeck's unqualified technical opinions, (3) Mr. Manbeck's understanding of the opinions of Defendants' technical experts, and

(4) Mr. Manbeck's opinions on intent to deceive. The Court should strike the Manbeck report because Mr. Manbeck's proposed testimony provides no admissible or helpful information to the Court in this bench trial.<sup>1</sup>

Mr. Manbeck has no pertinent technical background, and is not qualified to offer any opinions about materiality. Moreover, his testimony about disputed technical issues is limited to parroting the testimony of Par's technical witnesses. His opinions are cumulative and unhelpful.

To the extent Mr. Manbeck is permitted to testify, Plaintiffs will almost certainly find it necessary to offer testimony from a patent law expert of their own. This will further lengthen and complicate the trial. Striking Mr. Manbeck's report and precluding his testimony will obviate the need for rebuttal by an expert for Plaintiffs on these issues, and will simplify and shorten the trial.

### **III. STATEMENT OF FACTS**

#### **A. The Litigation**

The patents at issue in this case, U.S. Patent Nos. 6,254,887 B1 ("the '887 patent") and 7,074,430 B2 ("the '430 patent"), relate to formulations of controlled release tramadol, a pain medication ("analgesic"). The prior art and the other technical issues relate to the fields of chemistry, pharmaceutical science, pharmaceutical development and medicine. *See, e.g.*, the declarations submitted by Plaintiffs on claim construction (D.I. 159 and D.I. 160), in particular paragraphs 11-15 of the Declaration of Dr. Martyn C. Davies in Support of Plaintiffs' Opening Brief on Claim Construction (D.I. 160), which identifies the person of ordinary skill in the art for purposes of this action.

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<sup>1</sup> Plaintiffs also disagree with the substance of Mr. Manbeck's opinions, as well as with the opinions of the technical experts upon whom he allegedly relies.

## **B. Mr. Manbeck's Expert Report**

Mr. Manbeck asserts in his report that he is a lawyer with extensive experience at the PTO, including work as a former Commissioner of Patents and Trademarks. (Ex. A at ¶¶ 2-3.)<sup>2</sup> Mr. Manbeck has a degree in electrical engineering. (Ex. A at Exhibit 1.)

Despite his lack of expertise in the pertinent technology, the Manbeck report offers opinions on what the prior art discloses, the alleged materiality of technical information that was or was not disclosed to the PTO and his interpretation of experimental data. Mr. Manbeck also opines on the law and on the ultimate issue of whether Plaintiffs engaged in inequitable conduct before the PTO during the prosecution of the patents-in-suit.

After a discussion of some basic information regarding the patent prosecution process in general (Ex. A at ¶¶ 11-17), Mr. Manbeck offers several pages about the applicants' and their representatives' duty of candor and the doctrine of inequitable conduct (*id.* at ¶¶ 18-25). In doing so, he goes through his view of the law, citing various cases and Patent Office rules. (*Id.*)

The Manbeck report is also replete with opinions on materiality, and on what the Examiner would have done if certain information had been disclosed to him. The substance of Mr. Manbeck's opinions are summarized in the main headings of his report (Sections VII, VIII, IX and X):

- “VII. Materiality of U.S. Patent Application Serial No. 08/097,558 and Its Corresponding Issued Patent U.S. Patent No. 5,580,578” (Ex. A at 13);
- “VIII. Materiality of U.S. Patent No. 5,478,577” (*id.* at 19);
- “IX. Materiality of the Merck Reference Experiments By Napp To the Prosecution of the '887 Patent and the '430 Patent” (*id.* at 21); and

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<sup>2</sup> “Ex. \_\_\_\_” refers to Exhibit \_\_\_\_ to the Declaration of Reeta K. Whitney in Support of Plaintiffs' Motion to Strike Defendants' Expert Report of Harry F. Manbeck, Jr. filed concurrently herewith.

- “X. Materiality of a Third Malkowska Declaration During Prosecution of the ’887 Patent and the ’430 Patent” (*id.* at 68).

Although he is not a person of skill in the relevant arts, Mr. Manbeck offers his own interpretation of experimental data, technical declarations and technical expert reports. (*Id.* at ¶¶ 57-60, 67-73, 75-76, 88-90, 93-94, 100-07, 118, 130-31, 136-41, 143-44, 148-51, 154-61, 165.) For instance, Mr. Manbeck offers his opinion as to whether Plaintiffs’ arguments about experimental data were accurate in light of representations to the PTO. He states, for example:

- “Because the Momberger experiments and the Napp repeat experiments were inconsistent with the Malkowska declarations, they were material and a reasonable Examiner would have considered such information important in deciding whether to allow the application to issue as a patent.” (*Id.* at ¶ 109.)

In an apparent attempt to bolster his own unqualified technical opinions, Mr. Manbeck also relies extensively on the opinion of one of Par’s technical experts. For example:

- “They omitted information regarding formulations with PVA coating levels which all fell within the *in vitro* dissolution ranges set forth in at least claims 1-3, 7, 13-15 and 19 of the ’887 patent from their comments . . . . This has been confirmed by Par’s formulation expert, Dr. Palmieri.” (*Id.* at ¶92.)
- “I understand that it is the opinion of Par’s formulation expert, Dr. Palmieri, that it would be scientifically invalid to analyze data from one tablet as such data has no statistical significance, and that it would be scientifically proper to analyze mean data.” (*Id.* at ¶ 142.)
- “I understand that it is the opinion of Par’s formulation expert, Dr. Palmieri, that a reported observation of softening of the polyvinyl alcohol coating in acid medium would have caused him to question the reliability of the experiments and that he would not have relied on these experiments.” (*Id.* at ¶ 145.)

Based on his reliance on Par’s technical expert’s “confirmation,” Mr. Manbeck opines that “[b]ecause the Momberger experiments and the Napp repeat experiments were inconsistent with the Malkowska declarations, they were material and a reasonable Examiner would have considered such information important.” (*Id.* at ¶ 109.)

Mr. Manbeck offers similar unqualified opinions and relies upon Defendants' technical experts with respect to the purported nondisclosure of alleged prior art. For example, Mr. Manbeck opines that:

- "The '558 application and the '578 patent teach 'stable solid controlled release formulation[s] having a coating derived from an aqueous dispersion of a hydrophobic acrylic polymer [that] includes a substrate including an active agent,' such as tramadol." (*Id.* at ¶ 30.)
- "The '558 application and the '578 patent further teach that 'the oral solid dosage forms of the present invention provide a desired therapeutic effect for about 24 hours.'" (*Id.* at ¶ 31.)
- "The copending '558 application, I believe, was material to the patentability of the '798 application. Exhibit 8 illustrates the similarity and overlap in subject matter of the originally filed independent claims 42 and 63-65 of the '798 application on one hand and the originally filed and rejected claim 52 of the '558 application on the other hand." (*Id.* at ¶ 35.)
- "I understand it is the opinion of Par's formulation expert, Dr. Palmieri, that the '578 patent anticipates and/or renders obvious at least claims 1, 3-6, 13, 15-20, 22-27, 29-32 of the '887 patent and claims 1-17 of the '430 patent under 35 U.S.C. § 102(e)." (*Id.* at ¶ 32.)

Mr. Manbeck also provides legal opinions that amount to nothing more than attorney argument, on what is prior art (*id.* at ¶¶ 44, 52), what is a material omission (*id.* at ¶¶ 36, 42, 110) and how the Examiner would have responded to the allegedly withheld information (*id.* at ¶ 40). He also provides his own recitation of portions of the prosecution histories of the patents-in-suit. (*See, e.g.*, Ex. A at ¶¶ 26-27, 56-65, 74-83, 86-92, 95-104, 111-17.)

#### **IV. ARGUMENT**

##### **A. Patent Law Experts Are Routinely Precluded From Testifying Because Their Proposed Testimony Invades The Province Of The Court**

Federal Rule of Evidence 702 requires that a witness be qualified as an expert by knowledge, skill, experience, training or education:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill,



experience, training, or education, may testify thereto in the form of an opinion or otherwise. . . .

Moreover, an expert in one field cannot opine on issues in a different field in which he does not possess the “specialized knowledge” required by Rule 702. *Berry v. City of Detroit*, 25 F.3d 1342, 1349 n.6, 1351 (6th Cir. 1994).

Courts routinely exclude evidence that invades the province of the Court. *See United States v. Scop*, 846 F.2d 135, 140 (2d Cir. 1988) (expert’s opinions properly excluded where witness’ opinions were “legal conclusions that were highly prejudicial and went well beyond his province as an expert” and “were calculated to ‘invade the province of the court to determine the applicable law and to instruct the jury as to that law’”) (citation omitted).

It is well-established in this district that opinions by legal experts on issues of law are inadmissible.<sup>3</sup> *See Ondeo Nalco Co. v. EKA Chems., Inc.*, C.A. No. 01-537-SLR, slip op. at 9 (D. Del. Mar. 21, 2003) (striking expert report where patent law expert purported to opine “as to how the United States Patent and Trademark Office would have responded had certain prior art been disclosed to it during the prosecution of the ’805 patent”) (Ex. C); *L’Oreal S.A. v. Revlon Consumer Prods. Corp.*, C.A. No. 98-424-SLR, slip op. at 3 (D. Del. Feb. 24, 2000) (noting that patent law expert would not be permitted to offer “an opinion of law or an opinion as to ‘the thoroughness of the consideration of those issues’ considered by the examiner”) (Ex. D); *Lucas Aerospace, Ltd. v. Unison Indus., L.P.*, C.A. No. 93-525-JJF, slip op. at 2 (D. Del. Mar. 9, 1995) (patent law experts may not “draw inferences or make statements or conclusions about the

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<sup>3</sup> Judge Robinson’s Standing Orders include “Guidelines: Legal Expert Testimony in Patent Cases.” Those guidelines state: “‘Expert’ legal testimony (as opposed to technical testimony) on such substantive issues as invalidity (by anticipation, obviousness, on-sale bar, prior conception, etc.) and claim construction and infringement, generally is not admitted as descriptions of the law and instructions on the law are matters for the court.” (Ex. B.)

patent law of the case”) (Ex. E); *Thorn EMI N. Am., Inc. v. Micron Tech., Inc.*, C.A. No. 92-673-RRM, Tr. at 32-34 (D. Del. Nov. 23, 1993) (The Court does not “allow opinions on issues of law” or opinions “on what the significance may be on certain things that took place at the patent office.”) (Ex. F).

This Court also has made clear that patent law experts are unhelpful. In *F. Hoffman-La Roche, Ltd. v. IGEN International, Inc.*, C.A. No. 98-318-JJF, Tr. at 64 (D. Del. Oct. 24, 2000) (Ex. G), the Court stated that it “very consistent[ly]” excludes patent law experts in both bench and jury trials:

If you want assistance in preparing the case, hire him as special litigation counsel. If you want him to come under the rules of an expert witness, you are in a different ballgame. And in this district, when you get into that patent law/expert/et cetera area, we have a very consistent view. And the view is that they are not helpful. And not only do we mostly exclude them on Bench trials, but in jury trials they are so severely limited, I can’t figure out why anybody continues to propose them.

The Court has also consistently precluded expert testimony regarding patent practice and procedure because such testimony “is not required and will not be permitted except in the case of extraordinary circumstances.” (Ex. B; *accord Corning Inc. v. SRU Biosystems*, C.A. No. 03-633-JJF, slip op. at 2 (D. Del. Nov. 5, 2004) (patent lawyer’s “report and proposed testimony deal[ing] primarily with internal patent office procedures” excluded) (Ex. H)).

Patent law experts are also not permitted to offer opinions on inequitable conduct. *See Revlon Consumer Prods. Corp. v. L’Oreal S.A.*, No. 96-192 MMS, 1997 U.S. Dist. LEXIS 4117, \*9-10 (D. Del. Mar. 26, 1997) (precluding patent law expert from offering opinions on inequitable conduct because such testimony “would usurp the respective functions of the jury and the Court” and further noting that the holding precluded, among other things the proposed testimony concerning the “duties and responsibilities of an inventor, his or her attorney or agent,

and others substantively involved in the preparation and prosecution of a patent application in the PTO.”) (footnote and citation omitted).

The Manbeck report and Mr. Manbeck’s proposed testimony plainly violate these principles. The report should be struck and his testimony should be precluded for this reason above.

**B. Mr. Manbeck Cannot Testify About Materiality Because He Is Not Qualified To Testify About The Underlying Technology**

In addition to legal opinions, Mr. Manbeck offers opinions about the technical subject matter of the patents-in-suit and alleged prior art, and how a person of ordinary skill in the art would interpret experimental data and other expert reports even though he is not one skilled in the relevant arts. Mr. Manbeck purports to opine as to what certain prior art discloses and the proper interpretation of experimental data, and then compounds those unqualified opinions with the view that this information was material and should have been “effectively” disclosed to the patent examiner.

The standards by which information may be deemed material require an understanding of the significance of technical information to one of skill in the art. *See Digital Control*, 437 F.3d at 1315-16. Thus, only one skilled in the art can offer expert opinions about materiality. Mr. Manbeck does not qualify. *See Abbott Labs. v. Syntron Bioresearch, Inc.*, No. 98-CV-2359 H(POR), 2001 WL 34082555, at \*6 (S.D. Cal. Aug. 24, 2001) (If expert testimony is used to prove materiality, the expert must be qualified “to voice the understanding of a hypothetical person of ordinary skill in the art.”). 37 C.F.R. § 1.56(a) defines material art as art that is “not cumulative” to art that was cited. The similarity or difference between art that was not cited and art that was cited is an issue of disputed technical fact.

To the extent the issue of materiality turns on whether statements in the patents and prosecution histories were true or false as a matter of technical fact, Mr. Manbeck cannot opine on these issues. His proposed testimony is based not on his own technical knowledge or training -- he has none pertinent to this action -- but on things told to him by other experts. This is not proper expert testimony under Rule 702 because it is not based on any specialized knowledge or training of the witness.

**C. Mr. Manbeck's Opinions About Alleged Intent To Deceive The PTO Are Not Proper Expert Testimony**

Mr. Manbeck's proposed testimony is also not helpful with respect to intent to deceive the PTO. Such factual determinations are for the Court to make. Accordingly, under Rule 702, Mr. Manbeck's opinions on intent to deceive are inadmissible because his "expertise" is not needed to "assist the trier of fact to understand the evidence or to determine a fact in issue." *See Scop*, 846 F.2d at 140.

**V. CONCLUSION**

For the foregoing reasons, the Court should strike the expert report of Defendants' patent law expert, Harry F. Manbeck, Jr.

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